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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,447	02/05/2002	William H. Velander	030523-0185	4733

22428 7590 11/02/2004

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,447	VELANDER ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments filed August 12, 2004 have been fully considered but they are not persuasive. The declaration has been considered but is not fully persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is confusing as there is no indication that the transgenic pig is transgenic for a DNA sequence encoding human factor IX. A suggestion is that applicant amends the claim to state "in a transgenic pig whose genome comprises a DNA sequence encoding human factor IX."

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al (1992) Blood, Vol. 79, pp. 568-575.

Kim teaches the treatment of hemophilia B by administering 25 U/kg monoclonal body purified factor IX (page 569, col. 1, parag. 2, lines 1-3 and parag. 3, lines 4-6). The factor IX preparation demonstrated a specific activity of 180 to 200/U per mg, which is between 5 and 200% of the specific activity of human Factor IX isolated from plasma (page,

569, col.1, parag. 2, lines 15-21). Further, infusion of Factor IX to hemophilia patients raised Factor IX levels in blood 21% to 25% (page 570, col. 1, lines 7-11). While it is recognized that the claims require that the factor IX be from a transgenic pig, there are no characteristics of the Factor IX of the claims for its entire breadth of transgenic pig tissue source that distinguish it from the Factor IX of Kim. For this reason, Kim either clearly anticipates the claimed or renders obvious the claimed method of treating hemophilia B. At the time of the present invention, it would have been obvious to the ordinary artisan to treat hemophilia B by the claimed method in view of Kim teaching a method using Factor IX having the same properties.

Claims 19-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al (1992) Blood, Vol. 79, pp. 568-575.

Kim teaches biologically active human Factor IX that demonstrates a specific activity of 180 to 200/U per mg, which is between 5 and 200% of the specific activity of human Factor IX isolated from plasma (page, 569, col.1, parag. 2, lines 15-21). While it is recognized that the claims require that the factor IX be from a transgenic pig, there are no characteristics of the Factor IX of the claims for its entire breadth of transgenic pig tissue source that distinguish it from the Factor IX of Kim. For this reason, Kim either clearly anticipates the claimed or renders obvious the claimed Factor IX. At the time of the present invention, it would have been obvious to the ordinary artisan make the claimed Factor IX in view of Kim teaching Factor IX having the same properties.

"E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable

even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Applicant argues that the declaration by William Velander provides evidence that the factor IX isolated from transgenic pigs is not the same factor IX as disclosed in Kim. Applicant relies on the Velander declaration which states that the factor IX disclosed in the present application is produced in transgenic pigs and exhibits a longer half-life and mean residence time than that of plasma derived factor IX as described in Kim.

The declaration is not persuasive because it does not state from which pig tissue the human factor IX discussed in the declaration was isolated. The specification only discusses human factor IX produced and isolated from the milk of transgenic mammals, and in particular from the milk of transgenic pigs. However, the declaration does not state that the human factor IX was from the milk of transgenic pigs; only that the human factor IX was from pigs. The transgenic pig tissue source of the human factor IX is important because applicant is basing their non-obviousness on a physical property of the transgenically

produced factor IX. While evidence is not presented and such evidence is not needed, the increased half-life and mean residence time observed for the transgenic pig factor IX as compared to human plasma derived factor IX (Mononine™) might be due to post-translational modification differences. The post-translational modifications of declarant's factor IX could be because of production in the mammary gland, and the same modifications might not be made in other tissue sources, such as liver or muscle. Thus, declaration needs to submit another declaration stating the tissue source of the factor IX discussed, such as altering paragraph 3, line 5 to state "human factor IX isolated from the milk of transgenic pigs whose genome comprises a DNA sequence encoding human factor IX," or some other language to indicate that the human factor Ix discussed in the declaration is from the milk of transgenic pigs disclosed in the specification to produce human factor IX in their milk.

Further, and assuming that the human factor IX discussed in the declaration is isolated from the milk of transgenic pigs, the claims would need to be amended to indicate the tissue source of the factor IX in the claims. The declaration, the claims and the specification need to be commensurate in scope. For example, claim 1 can be amended to "biologically active human factor IX isolated from the milk of at least one transgenic pig whose genome comprises a DNA sequence encoding human factor IX," or other such language to clearly state the tissue source and the transgenic pig source of the human factor IX in the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

October 26, 2004